

**REMARKS**

***Status of the Claims***

In the present Amendment, Claim 61 has been added. Support is found in Claim 33.

Upon entry of the Amendment, Claims 29-61 will be pending, of which Claims 43-58 are withdrawn from consideration.

***Response to the Examiner's Alleged Section 112 Rejections***

(A) Referring to page 6 of the Office Action, Claims 59 and 60 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Applicant respectfully traverses.

The Examiner alleges that it is unclear whether the “pod” or the “tubular member”<sup>1</sup> is “including a thin-walled distal portion of the catheter tubular body of reduced wall thickness relative to a proximal portion of the catheter tubular body.” The underlined recitation is found in independent Claims 59 and 60. The underlined recitation (and, in fact, the entire clause containing the underlined recitation) is identical in Claims 59 and 60. The clause is reproduced below (with emphasis added) for purposes of this discussion:

a tubular medical device embracing pod located at the distal end of the catheter tubular body for reception of the medical device, the pod being integrally formed with the catheter tubular body and including a thin-walled distal portion of the catheter tubular body of reduced wall thickness relative to a proximal portion of the catheter tubular body, and the pod having a greater flexibility than the proximal portion of the catheter tubular body

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<sup>1</sup> For clarity, Applicant points out that recitation “tubular member,” as per the Examiner, is not found anywhere within the claims. Instead, the claims recite a “catheter tubular body.”

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Applicant points out that independent Claim 29 also contains the exact same underlined portion (and surrounding clause), but the Examiner has not addressed this recitation in Claim 29.

The subject clause of Claim 29 is reproduced below (with emphasis added):

a tubular medical device embracing pod located at the distal end of the catheter tubular body for reception of the medical device, the pod being integrally formed with the catheter tubular body and including a thin-walled distal portion of the catheter tubular body of reduced wall thickness relative to a proximal portion of the catheter tubular body, and the pod having a greater flexibility than the proximal portion of the catheter tubular body

This clause, including the underlined portion, has been pending, and has been examined multiple times, since August 30, 2005.

Despite the fact that the Examiner found this portion of Claim 29 to be clear and definite throughout examination and in the present action, the Examiner alleges that this recitation is indefinite in Claims 59 and 60, and improperly made the most recent Office Action final.

First, Claims 59 and 60 (and also Claim 29) are clear and definite. The above-reproduced clause of Claims 29, 59 and 60 is clearly directed to the structure of the “tubular medical device embracing pod” or simply the “pod.” The clause introduces the pod element into the claims. Likewise, beginning with the first comma “,” of the clause, the structure of the pod is defined as being “integrally formed with the catheter tubular body” and including “a thin-walled distal portion of the catheter tubular body.” It is clear that the “thin-walled” portion is referring to a structure of the pod. Likewise, the claims expressly recite that the “thin-walled” distal portion defining the pod is “relative” to a proximal portion of the catheter body. The Examiner is disregarding the recitation “including.”

Second, even if it could be said that it is ambiguous whether the reduced thickness is in the pod or the tubular member, which is a position that Applicant completely disagrees with for

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the reasons above, one of ordinary skill in the art would find the claims clear and definite in light of the specification, particularly the figures and corresponding description.

In view of the above, reconsideration and withdrawal of the Section 112, second paragraph, rejection of Claims 59 and 60 are respectfully requested.

(B) Referring to page 6 of the Office Action, Claim 29 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Applicant respectfully traverses.

The Examiner alleges that it is “unclear from the claim whether ‘embolic protection filter’ carries more elements than simply a mesh.” The Examiner also questions “What does an ‘embolic protection filter’ entail, or is it simply a tubular membrane?”

Applicant submits that Claim 29 is clear and definite. One of ordinary skill in the art at the time of the invention would have readily appreciated and understood the meaning of the well-known term “embolic protection filter.”

The specification also addresses the term embolic protection filter. For example, the first substantive paragraph of the specification, addressing the field of the invention, discloses that “The present invention relates to a medical catheter and more particularly to a catheter for the transvascular deployment of expandable medical devices, such as an intravascular embolic filter device, in a collapsed condition.” *See* paragraph [0001] of the USPTO’s publication of the present application. The next paragraph reads “The device as described herein relates to a carotid angioplasty procedure with an intravascular filter being placed distally to capture procedural emboli being released.” Moreover, the next subsequent paragraph incorporates by reference one of Applicant’s copending applications, which describes a useful embolic protection

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filter (PCT\IE98\00093). Applicant also kindly directs the Examiner's attention to FIG. 7 of the present application, which illustrates the structure and design of one embolic protection filter.

Furthermore, Applicant points out that, faced with the amendment to Claim 29 reciting that the claimed medical device is an "embolic protection filter," the Examiner was able to find (and cite) a reference (i.e., Daniel) teaching an embolic protection device, titled "Distal Protection Device and Method," filed October 1997.

Finally, Applicant submits that, in discussing this claim amendment, Applicant's arguments did not require any particular structure over what would have been commonly understood by one of ordinary skill in the art at the time of the invention. In sum, one of ordinary skill in the art at the time of the invention would have appreciated that an embolic protection filter is simply different from the implant of Dwyer.

In view of the above, reconsideration and withdrawal of the Section 112, second paragraph, rejection of Claim 29 are respectfully requested.

***Response to the Examiner's Alleged Section 103 Rejections***

Referring to page 3 of the Office Action, Claims 31, 34 and 39-42 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over USPN 6,395,017 (Dwyer) in view of USPN 6,001,118 (Daniel).

Applicant traverses and respectfully requests the Examiner to reconsider in view of the following remarks. The present claims are patentable over the Dwyer/Daniel combination for *at least* the following reasons.

Claim 32, which directly depends from independent Claim 29, and independent Claims 59 and 60 require the following structural element:

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an outer diameter of the catheter tubular body is substantially constant from the proximal portion to the distal portion

However, the Examiner has failed to address this structural element anywhere within the present Office Action.

Accordingly, Applicant respectfully submits that the rejection based on the Dwyer/Daniel combination was improper and did not establish a proper *prima facie* case of obviousness because it did not point to any disclosure in any cited reference of “an outer diameter of the catheter tubular body is substantially constant from the proximal portion to the distal portion.” Without addressing this element, there is a clear deficiency in the asserted *prima facie* case in support of the rejection. Thus, this improper rejection should be withdrawn.

In addition, Applicant submits that the Dwyer/Daniel combination does not disclose or suggest “an outer diameter of the catheter tubular body is substantially constant from the proximal portion to the distal portion” in view of the position the Examiner has taken for the other claim elements.

The Examiner asserts, in the Advisory Action, that “the rejections are proper because all structures are taught and are fully capable of performing all claimed functional, spatial, and operational limitations (see previous Office Action rejections).”

Applicant disagrees. As set forth in the Rule 116 Response and herein, the Examiner failed to address all of the structural elements of the present claims (i.e., “an outer diameter of the catheter tubular body is substantially constant from the proximal portion to the distal portion”). Thus, simply referring to the Examiner’s “previous Office Action rejections” does not cure the Examiner’s failure to establish a *prima facie* case of obvious.

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Further, the Dwyer/Daniel combination fails to even suggest this structure given the position the Examiner has taken regarding where the other structural elements can allegedly be found in Dwyer. For example, the Examiner has taken the position that the catheter tubular body of Dwyer has a thin walled distal portion relative to the proximal portion of the catheter tubular body by defining the catheter tubular body as element **20** (per the Examiner, the thick portion) to element **22** (per the Examiner, the thin portion) of Dwyer. (Office Action at p. 3.) Thus, it is clear that an outer diameter of the catheter tubular body would not be substantially constant from the proximal portion to the distal portion, as defined by the Examiner.

In view of the above, reconsideration and withdrawal of the Section 103 obviousness rejection of the present claims based on Dwyer in view of Daniel are respectfully requested.

***Conclusion***

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the local, Washington, D.C., telephone number listed below.

Respectfully submitted,

/Michael G. Raucci/

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